

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Richard L. PELLEGRINI et al.

Group Art Unit: 3772

Application No.: 09/988,335

Examiner: M. BROWN

Filed: November 19, 2001

Docket No.: 106679.01

For: DISPOSABLE EYE PATCH AND METHOD OF MANUFACTURING A
DISPOSABLE EYE PATCH

REQUEST FOR RECONSIDERATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the February 27, 2007 Office Action, reconsideration is respectfully requested in view of the following remarks. Claims 24-40, 45, 58-59 and 63-99 are pending.

Applicants thank Examiners Brown and Bianco for the courtesies extended to Applicants' representative during the February 27 personal interview. During the interview, Applicants' representative explained why the secondary references applied in the new rejections, including the newly cited U.S. Patent No. 5,190,810 to Kirschbaum et al. ("Kirschbaum"), would not have made it obvious to one of ordinary skill in the art to modify the Langley reference (U.S. Patent No. 4,969,472) in the manner proposed by the Office Action. The Examiners did not rebut the points made in this regard, but asserted that it may have been obvious instead to have modified Kirschbaum in view of U.S. Patent No. 2,527,947 to Loos. Applicants' representative asserted that there would have been no motivation for such a combination, and the Examiners did not disagree with the points made.

In addition to the points made during the interview, Applicants note the following regarding the unofficially proposed modification of Kirschbaum in view of Loos. Loos, cited for a teaching of "entirely within a human eye socket in at least one dimension of the eye socket," does not suggest such a feature in a context that is relevant to the Kirschbaum disclosure. Specifically, the Loos device is "designed for use ... when a sun bath is to be taken, ... [or] when it is desired to rest the eyes." (Col. 1, lines 1-4). At column 2, lines 37-51, it is disclosed that forming the Loos device so that its edges abut the walls of the eye socket helps prevent the device from being blown off by wind.

In contrast, the composite material disclosed by Kirschbaum is for use in laser surgery. There is no evidence that wind blowing a patch off of an eye would have been recognized by those skilled in the art as a problem in laser surgery. Furthermore, because the Kirschbaum composite material has adhesive on its surface, the adhesive would have prevented any such blowing away, without the need for lodging edges of the material against the walls of an eye socket.

Furthermore, with respect to dependent claims 25, 70 and 85, Applicants' representative pointed out during the interview that when the composite material of Kirschbaum is cut to size, it clearly does not have a metallic layer (claims 25 and 85) or laser-resistant layer (claim 70) that does not overlap a peripheral portion of the sheet member. The Office Action asserts that Kirschbaum discloses such a feature in Fig. 1, but Fig. 1 appears to simply show the free end of a roll of composite material, before it is cut to a desired size. Although not described, it appears that the free end apparently is formed as depicted so that a small area of the adhesive layer 18 is exposed so that the free end can be self-adhered to the roll 30 (Fig. 2) so that it stays in the wound configuration for packaging and shipping purposes. It is clear from the context that this free end is cut off and discarded in use.

For convenience, repeated below, and modified as appropriate to refer to the Kirschbaum reference, are some of Applicants' previously stated exemplary reasons regarding why it would not have been obvious to modify the Langley device to be small enough to fit entirely within a human eye socket in at least one dimension of the eye socket, as recited in claims 24, 68 and 83, and/or to have a metallic layer with a plan view shape that is continuous over an eyeball-covering area, as recited in claim 24, and/or to make the Langley patch 12 a laser-resistant layer of foil or film, as recited in claim 68, and/or to have the "sheet member" 20 of Langley be on only one side of the metallic layer, as recited in claim 83. It is noted that the newly cited reference of Kirschbaum does not explicitly or implicitly rebut these points. The new Office Action also does not rebut them, and they were not rebutted during the personal interview.

A. Independent Claim 24

The Office Action recognizes that Langley does not disclose the "fit entirely within a human socket in at least one dimension of the eye socket" feature, but asserts that Loos would have made this feature obvious in the Langley device, to "prevent the pad from being dislodged from the eye socket." The Office Action also recognizes that Langley does not disclose the "plan-view shape being continuous over the eyeball-covering area" feature of claim 24, but asserts that this feature would have been obvious in view of Loos and/or Kirschbaum. However, the Office Action's analysis errs with respect to claim 24 on several points, discussed below.

1. The Proposed Modifications Would Eliminate Langley's Pores, Which Are Important To The Operation Of The Langley Device

The "eyeball-covering area" of the Langley eye patch includes pores 16, and therefore is not continuous. The pores 16 are important to the Langley eye patch "to provide a steady inflow of air," as can be seen from, e.g., col. 3, lines 32-36. The importance of the pores 16 is

particularly apparent from the fact that, even when it is desired to prevent light from entering the eye, Langley does not teach that the pores 16 should be eliminated, but rather teaches that cotton, gauze or other material should be placed behind the patch (col. 3, lines 34-36). Thus, it would not have been obvious to make the Langley metallic layer continuous at the eyeball-covering area, despite any teaching of Loos, Kirschbaum or any other reference.

2. The Alleged Motivation To Combine Is Without Merit

As the motivation to combine Brink with Langley, the Office Action asserts that Kirschbaum's disclosed sheet "could be substituted for the sheet 10 disclosed by Langley in order to have a flat sheet." However, the Langley apparatus relies on element 10 being in a tubular form, instead of a flat sheet form. See, for example, column 3, lines 37-57, which explain that the "perimeter garter 10" is "advantageously formed by rolling a sheet of foamed plastic into a cylinder, and, after joining the ends of the rolled sheet permanently together, slicing the cylinder to form plural circular strips." This passage goes on to explain that one of these circular strips forms the garter 10, and that the garter 10 is stretched over the edge of the patch 12, and is held in place by its own resilience. Thus, Langley clearly teaches away from a "flat sheet," and therefore the alleged motivation to combine is without merit.

3. The Langley Device Already "Prevents From Dislodging," Without Modification

In asserting that there would have been no motivation to modify Langley in view of Loos to fit entirely within an eye socket in at least one dimension, Applicants previously pointed out that the Langley eye patch is already prevented from being dislodged because it is held in place by tape or a headband, and thus it would not have been obvious to size it to fit inside the eye socket for the purpose of preventing it from being dislodged. In response to this point, the March 8, 2006 Office Action simply states, "Langley was used to set forth the environment of the patch. Loos was used as a modifier to make the eye patch so it fits inside

of the eye socket. Whether the tape or the headband is used to hold the eye patch in place is moot."

That response does not fit within the legal framework of an obviousness analysis. Even though "Langley was used to set forth the environment of the patch," that environment is very relevant to the issue of motivation, and must be considered in its entirety. Langley's disclosed tape or headband holding the eye patch in place are part of the disclosed environment, and refute the March 8, 2006 Office Action's position that there would have been motivation to hold the patch in place in some other way. Therefore, "whether the tape or the headband is used to hold the eye patch in place" is not "moot," but rather bears heavily on the issue of motivation.

Furthermore, it is noted that the current Office Action does not respond to this point.

4. Modifying the Langley Device To Fit Within an Eye Socket In At Least One Dimension Would Be Contrary To Langley's Teachings

Applicants asserted that it would not have been obvious to one of ordinary skill in the art to size the Langley eye patch to fit within the human eye socket in at least one dimension, because doing so would be contrary to Langley's teachings. The Langley eye patch is intended to protect a wearer's eye "during a post-surgery period or after injury to the eye" (col. 1, lines 14-15). If the eye patch were sized to fit inside the eye socket, it would be difficult or impossible to apply the eye patch without putting some pressure, or risking putting some pressure, on the sensitive eye, which clearly would be undesirable for an eye that has been injured and/or surgically operated upon.

In its response, the March 8, 2006 Office Action does not correctly address the issue of obviousness, instead addressing the issue as a matter of what the prior art is "capable" of doing. The March 8, 2006 Office Action completely fails to respond to the

point that, if the Langley eye patch were modified as suggested (i.e., to be small enough to fit within the eye socket), it would not be suitable for its disclosed intended use. The issue of whether the device may be capable of other, undisclosed uses is not relevant here. The fact is that the proposed modification would make the device unsuitable for its intended purpose, which is contrary to the law governing the obviousness analysis. See, e.g., MPEP §2143.01.V., entitled "THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE." The March 8, 2006 Office Action's position on this point does not satisfy the law explained in this section of the MPEP.

Furthermore, it is noted that the current Office Action does not respond to this point.

* * *

For any or all of the foregoing reasons, the rejection of independent claim 24 is in error. The additional references applied against dependent claims do not overcome the above-noted deficiencies of Langley, Loos and Kirschbaum with respect to claim 24. Accordingly, the claims dependent from claim 24 are allowable at least for their dependence on an allowable base claim.

B. Independent Claim 68

Claim 68 recites, *inter alia*, a laser-resistant layer of foil or film attached to the sheet member. The metallic layer of Langley is rigid (see, e.g., col. 1, lines 19-21), and it would have been readily recognized by those skilled in the art that Langley's metallic layer is not a foil or film. Furthermore, it would not have been obvious to make Langley's metallic layer a foil or film, at least for the reason that doing so would very likely result in the metallic layer being crushed when the garter 10 is stretched around its edge, as described at col. 3, line 54-col. 4, line 4, for example.

For at least this reason, claim 68 and all claims dependent therefrom are patentably distinct from the applied prior art.

C. Independent Claim 83

The Office Action, like the previous Office Action, fails to address claim 83 other than to say it is rejected over Langley in view of Loos and Kirschbaum.

Claim 83 recites, *inter alia*, a sheet member and a metallic layer that protects an eye from laser light, the sheet member being on only one side of the metallic layer. In contrast, in the Langley eye patch, the garter 10 (sheet member) is on both sides of the metallic layer, and must be so in order to operate in the designed manner as described at, for example, col. 3, line 54-col. 4, line 34.

Accordingly, claim 83 and all claims dependent therefrom (i.e., new claims 84-98) are patentably distinct from the applied prior art.

D. The Office Has Not Established a *Prima Facie* Case of Obviousness Regarding Claimed Thicknesses Or Materials

The various dependent claims reciting specific materials, thicknesses or ranges of thickness of the sheet member or metallic layer have not been adequately addressed by the Office Action. The Office Action rejects these claims simply on the basis that the dimensions or materials in the claims are "design choice" and/or are "not critical." The Office cannot shift the burden of proof on this point without first establishing a *prima facie* case of obviousness. Applicant maintains that the rejection of these claims continues to be improper because the Office has not met its burden of establishing a *prima facie* case of obviousness.

Regarding "design choice," the Office Action simply states a conclusion. This is improper, as held by the Board of Patent Appeals and Interferences in, e.g., *In re Garrett* (Appeal No. 580-81, decided September 30, 1986). Specifically, the Board held that the

Examiner's assertion of "design choice," unsupported by any line of reasoning regarding motivation, was "a conclusion, rather than a reason" (*In re Garrett*, slip op. at page 4, copy submitted with the November 15, 2006 Amendment).

Regarding criticality, the MPEP explains that a showing of criticality, or unexpected results, "can rebut a *prima facie* case of obviousness based on overlapping ranges" (MPEP §2144.05, emphasis added). In other words, when the prior art discloses a range that overlaps the claimed range, then the applicant must show the criticality of the claimed range in order to rebut the *prima facie* case of obviousness established by that disclosure in the prior art.

In this case, however, the prior art does not even discuss thicknesses, and does not disclose various ones of the materials claimed. Thus, a *prima facie* case of obviousness, e.g., evidence of overlapping ranges, has not been established. It is improper to require a showing of criticality in such a situation.

Should the Office maintain its position that it need not first establish a *prima facie* case of obviousness to shift the burden to Applicants to show criticality, Applicants respectfully request citation of a rule or case supporting such position.

* * *

Accordingly, all of the pending claims are patentably distinct from the applied references. Applicants respectfully request reconsideration and withdrawal of the rejections.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 24-40, 45, 58-59 and 63-99 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, or that the application is for any reason not yet in condition for allowance, the Examiner is requested to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



William P. Berridge
Registration No. 30,024

J. Adam Neff
Registration No. 41,218

WPB:JAN/scg

Date: March 8, 2007

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

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